REMARKS

A. Status of the Claims and Amendments

Claims 1-32 were filed in the instant application. Claims 1-2 and 4-32 are currently pending. Claim 3 was canceled by amendment dated April 19, 2004.

Claim 2 stands rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 1-2 and 4-32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Herman, further in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, or Weiner *et al.* Claims 1-2 and 4-32 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 99/00120, further in view of Sugarman *et al.*, Ranade *et al.*, Mayer *et al.*, or Weiner *et al.* Claims 1-2 and 4-32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hermann or WO 99/00120, in view of Presant.

The specific grounds for rejection and applicants' response to them are set forth in detail below. Further, claim 24 is herein amended to remove extraneous language. Claim 26 is herein amended to correct a minor typographical error. Support for the claims as presently written, including the amended claims, is found within the specification. The present amendments do not introduce new matter. In view of the arguments set forth below, claims 1-2 and 4-32 are presented for reconsideration.

B. Rejection Under 35 U.S.C. § 112

Claim 2 stands rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claim 2 recites "[t]he pharmaceutical composition of claim 1, wherein at least a portion of the phospholipids comprise micelles." According to the examiner, there is no support in the specification for this claim. Applicants traverse.

The objective standard for determining compliance with the written description requirement is whether "the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *Manual of Patent Examining Procedure* (*MPEP*), §2163.02, citing *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). To clearly satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. *MPEP*, §2163.02, citing *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

Applicants draw the examiner's attention to the specification, which provides substantial detail providing that in certain embodiments, the term "lipids," as used in the specification, encompasses "phospholipids." Specifically, the specification provides that "[i]n certain embodiments, the lipid or lipids comprise at least one phospholipid." Specification, page 5, lines 20-21. Particular examples of phospholipids are provided thereafter. See Specification, page 5, lines 20-29. In addition, a detailed discussion concerning phospholipids can be found in the specification on page 26, lines 8-26. In view of these sections of the specification, one of ordinary skill in the art would understand that phospholipids are encompassed by the term "lipids" in the context of the present invention.

Furthermore, the specification clearly conveys that in certain embodiments, at least a portion of the lipids could comprise micelles. In particular, the specification clearly states that **"[i]n certain embodiments, at least a portion of the lipids comprise micelles."** Specification, page 5, line 30 (emphasis added). The specification also provides that:

> An imexon and/or a derivative thereof associated with a lipid may be dispersed in a solution containing a lipid, dissolved with a lipid, emulsified with a lipid, mixed with a lipid, combined with a lipid, covalently bonded to a lipid, contained as a suspension in a lipid or otherwise associated with a lipid. A lipid

> or lipid/imexon and/or a derivative thereof associated composition of the present invention is not limited to any particular structure. For example, they may also simply be interspersed in a solution, possibly forming aggregates which are not uniform in either size or shape. In another example, they may be present in a bilayer structure, as **micelles**, or with a "collapsed" structure.

Specification, page 28, lines 16-23 (emphasis added). In addition, the specification contains an entire section pertaining to micelles and lipid compositions that include micelles. In particular, the specification provides that:

> **A lipid may be comprised in a micelle.** A **micelle** is a cluster or aggregate of lipid compounds, generally in the form of a lipid monolayer, and may be prepared using any micelle producing protocol known to those of skill in the art (*e.g.*, Canfield *et al.*, 1990; El-Gorab *et al.*, 1973; Colloidal Surfactant, 1963; and Catalysis in Micellar and Macromolecular Systems, 1975, each incorporated herein by reference). For example, one or more lipids are typically made into a suspension in an organic solvent, the solvent is evaporated, the lipid is resuspended in an aqueous medium, sonicated and then centrifuged.

Specification, page 30, lines 8-15 (emphasis added). Thus, the specification provides that (1) phospholipids are a type of lipid that can be used in the context of the present invention, and (2) lipids, as the term "lipid" is defined herein, may be comprised in a micelle. Therefore, one of ordinary skill in the art, upon reading this specification, would understand that phospholipids may be comprised in a micelle. Therefore, the application clearly conveys compositions wherein at least a portion of the phospholipids are comprised in micelles. Consequently, one of ordinary skill in the art, upon reading the specification, would understand that the inventors had possession of the claimed invention.

Accordingly, there is ample written description support in the specification for present claim 2. Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

C. Rejection under 35 U.S.C. § 103(a)

1. Rejection of claims 1-2 and 4-32 as being unpatentable over Hermann, further in view of either Sugarman et al., Ranade, Mayer et al., or Weiner et al.

Claims 1-2 and 4-32 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hermann, further in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, or Weiner *et al.* The examiner contends that Hermann discloses compositions containing imexon and a lipid, specifically magnesium stearate. Sugarman *et al.* is said to teach (1) that liposomes are sustained release agents and that they are advantageous as carriers of drugs because they reduce toxicity associated with those drugs; (2) the use of DMPC/DMPG in a ratio of 7:3; and (3) the attachment of monoclonal antibodies to the surface of liposomes to direct the liposomes to the target tissue as being known in the art. Ranade is said to disclose advantages of using liposomes as carriers of drugs, and the sustained release and site-specific release of drugs. Mayer *et al.* is said to teach the tumor uptake and anti-tumor efficacy of doxorubicin against murine mammary tumors. Weiner *et al.* is said to teach the advantages of using liposomes as carriers of drugs, and their sustained release and site-specific release of drugs.

According to the examiner, the use of liposomes as carriers of imexon would have been obvious to one of ordinary skill because of the advantages of liposomes taught by Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.* Further, the examiner contends that the use of phosphatidylcholine and phosphatidylglycerol with a specific fatty acid chain such as myristic acid is not readily apparent in the absence of unexpected results since Sugarman *et al.* evidences that these are commonly used. Furthermore, the use of derivatives of imexon is said to be obvious to one of ordinary skill since the active skeleton is the cyaozairidine skeleton. The examiner, citing Presant, now includes claim 2 in the rejection since liposomes are also said to be called micelles. Applicants traverse.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. *MPEP* § 2142. See also *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed Cir. 1991) (emphasizing that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must be both found in the prior art, and not based on applicant's disclosure). It is important to note that all three elements must be shown to establish a *prima facie* case of obviousness. Thus, if one element is missing, a *prima facie* case of obviousness does not exist.

As noted above, in order for a *prima facie* case of obviousness to exist, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the teachings of Hermann in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.* "The mere fact that references can be combined or modified does not render the resultant combination obvious ***unless the prior art also suggests the desirability of the combination***." *MPEP* § 2143.01 (emphasis added). None of these references makes any suggestion of delivering imexon via administration of liposomes. Hermann discloses delivery of imexon with ***oils***, not phospholipids or liposomes. Similarly, Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.* teach the use of liposomes in drug delivery, but never mention imexon as a possible drug.

Consequently, the issue is whether one of ordinarily skill in the art, with knowledge that is generally available, would be motivated to combine Hermann in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.* Many drug therapies have been investigated in

treating cancer, but in two of the references that discuss liposomal drug delivery, Mayer *et al.* and Weiner *et al.*, only one drug is mentioned, doxorubicin. None of these references make any recommendations as to which cancer drugs may be suitable for liposomal delivery other than doxorubicin. Sugarman *et al.* states that "most of the chemotherapeutic agents used have been doxorubicin or cisplatin derivatives." Sugarman *et al.* also mentions use of muramyl peptides with liposomes. Ranade discloses use of liposomes with doxorubicin, cisplatin, and macrophage activation factors. However, none of the drugs mentioned have any similarity or structural resemblance to imexon. Hundreds of drugs exist for treating cancer such that one skilled in the art could not possibly know that imexon would be a drug appropriate for liposomal delivery. Furthermore, since Hermann does not explicitly state that such use would be possible, one skilled in the art would have even less motivation to combine the references. Therefore, Hermann in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.* fails to establish an element necessary for a *prima facie* case of obviousness.

Applicants disagree with examiner's contention that there is clear motivation to one of ordinary skill in the art to combine reference teachings. In support of this contention, the examiner asserts that "Sugarman *et al.*, and Ranade in particular teach the advantages of using liposomes as sustained delivery agents for both hydrophobic and hydrophilic active agents, cancer agents in particular and that of Mayer *et al.* shows the increased uptake of liposomes containing an anti-cancer drug by the tumor cells." However, as noted above, hundreds of drugs exist for treating cancer. One of ordinary skill in the art could not possibly know that imexon would be a drug appropriate for liposomal delivery, and the examiner's unsupported conclusion to the contrary cannot be accepted merely at face value. Further, the examiner's contention that "liposomal art is well advanced in the sustained delivery of a variety of drugs and therefore, motivation to use liposomes comes from the knowledge available to one of ordinary skill in the

art" (Office Action, paragraph 1, page 5) fails to address the issue at hand, which is the question of delivery of a particular compound - imexon.

The examiner further contends that "the novelty is the sustained delivery nature of the liposomes themselves and this sustained delivery does not depend upon the drug encapsulated and therefore, one of ordinary skill in the art would expect at least the same results using imexon as the drug." Office Action, paragraph 1, page 5. The examiner appears to be contending that use of imexon would be obvious since liposomes have been successfully used to deliver other types of drugs, and that this is sufficient to establish obviousness for the delivery of ***any*** drug. However, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so, either explicity or implicity, found in the references themselves or in the art. MPEP §2143.01. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." MPEP §2143.01, citing *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000).

In *In re Kotzab*, the claims were drawn to an injection molding method using a single temperature sensor to control a plurality of flow control valves. The primary reference disclosed a multizone device having multiple sensors, each of which controlled an associated flow control valve, and also taught that one system may be used to control a number of valves. The court found that there was insufficient evidence to show that one system was the same as one sensor. While the control of multiple valves by a single sensor rather than by multiple sensors was a "technologically simple concept," there was no finding "as to the specific understanding or principle within the knowledge of the skilled artisan" that would have provided motivation to use a single sensor as to the system to control more than one valve. *In re Kotzab*, 217 F.3d at 1371.

In re Kotzab appears to apply in the facts at hand. The examiner appears to be of the opinion that one of ordinary skill in the art would find that use of imexon in liposomes is obvious because of the success of liposomes in delivering other drugs, and is thus obvious. However, as noted in *In re Kotzab*, such an assertion is not sufficient to render a case obvious. There must be some finding as to the specific understanding or principle within the knowledge of the skilled artisan that would have provided motivation to use imexon in liposomes. No such finding has been established, and thus the examiner's argument fails.

Another element in establishing a *prima facie* case of obviousness requires that there be a reasonable expectation that modifying the teachings of Hermann in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.* would be successful. Applicants, in their previous response, have submitted that there would be no reasonable expectation of success in combining imexon and liposomal delivery in treating cancer. The examiner has failed to provide evidence that combining imexon and liposomes would reasonably result in success.

The result of combining drug therapies is impossible to predict. The examiner appears to merely assume that combining imexon and liposomal drug delivery will automatically result in success. There simply is no basis for such an assumption. Furthermore, none of the five references provide any guidance or recommendations as to whether combining imexon with liposomal drug delivery would be successful in treating cancer. At best, the prior art presents an "obvious to try" situation. Specifically, the combination of imexon and liposomal delivery may or may not be successful. However, the PTO's reviewing court has consistently held that "'obvious to try' is not the standard" and "does not render a claim obvious." *Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 56 U.S.P.Q.2d 1065 (Fed. Cir. 2000), *In re Roemer*, 258 F.3d 1303, 59 U.S.P.Q.2d 1537 (Fed. Cir. 2001).

In view of the prior art, a person of ordinary skill in the art could not reasonably expect to achieve success in administering imexon via liposomal delivery. As a result, Hermann in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.* does not establish a reasonable expectation of success as required for a *prima facie* case of obviousness.

Further, Presant, cited by the examiner as of interest, is said to teach that liposomes are also called micelles. This fails to address the missing element of expectation of success. Presant pertains to methods of targeting locations in a body using micellular particles. It contains no information pertaining to delivery of imexon via liposomal delivery.

In view of the above arguments, examiner has not established a *prima facie* case that claims 1-2 and 4-32 were obvious at the time of filing. Accordingly, applicants respectfully request that the rejection of claims 1, 3-10, 12, 25-32 be withdrawn.

2. Rejection of claims 1-2 and 4-32 as being unpatentable over WO 99/00120, further in view of Sugarman et al., Ranade, Mayer et al., or Weiner et al.

Claims 1, 3-32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO '120, further in view of either of the following references: Sugarman *et al.*, Ranade, Mayer *et al.*, or Weiner *et al.* WO '120 is said to disclose imexon and several of the claimed derivatives for treating cancer, and use of imexon in combination with other anti-cancer agents. The examiner notes that "what is lacking in WO is the teaching of the use of liposomes as carriers for the delivery of imexon or its derivatives for the treatment of cancer or stimilating the immune system." Office Action, paragraph 3, page 6. It is purported that WO '120 teaches the use of slow release carriers. The teachings of Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.* are discussed *supra*. According to the examiner, the use of liposomes as carriers for imexon or its derivatives taught by WO '120 would have been obvious to one of ordinary skill in the art

because of the advantages of liposomes taught by Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.* The examiner considered arguments set forth in the response to the previous rejection under 35 U.S.C. §103 (a) set forth in the response to the previous Office Action to the above 35 U.S.C. §103(a) rejection, and found them unpersuasive, noting that the response set forth above applies to this rejection. Applicants traverse.

As noted above, in order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. *MPEP* § 2142. See also *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed Cir. 1991). All three elements must be shown to establish a *prima facie* case of obviousness. If one element is missing, a *prima facie* case of obviousness has not been established.

In light of the reasons presented in the previous section, which apply as well to this section, Applicants disagree that claims 1-2 and 4-32 are obvious over WO '120 in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, or Weiner *et al.* Furthermore, Applicants submit the following arguments against the examiner's assertion of obviousness.

An element that is required in order for a *prima facie* case of obviousness to exist is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the teachings of WO '120 in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, or Weiner *et al.* None of these references make any suggestion of using liposomes as a carrier of imexon and its derivative.

Therefore, the relevant inquiry is whether one of ordinarily skill in the art, with knowledge that is generally available, would be motivated to combine WO '120 in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.* Applicants disagree that one of ordinary skill in the art would be motivated to do so. Applicants reiterate that many therapies and drugs are available in treating cancer. Although Sugarman *et al.* provides examples of using liposomes as a carrier of cancer drugs such as doxirubicin and cisplatin, it does not suggest which additional cancer drugs could be delivered using liposomes. As a matter of fact, neither Ranade, Mayer *et al.*, nor Wiener *et al.* makes any recommendation as to potential types of cancer drugs which may warrant future investigation. In view of the myriad of cancer drugs available and the lack of suggestion in the prior art, a skilled artisan would have no motivation to specifically use liposomes as a carrier for imexon and its derivatives. Thus, WO '120, in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.*, fails to establish an element required for a *prima facie* case of obviousness.

Another element in establishing a *prima facie* case of obviousness requires that there be a reasonable expectation that modifying the teachings of WO in view of either Sugarman *et al.*, Ranade, Mayer *et al.*, and Weiner *et al.* would be successful. Applicants submit that there would be no reasonable expectation of success in combining imexon derivatives and liposomal delivery in treating cancer. The examiner presents no evidence that combining imexon derivatives and liposomes would reasonably result in success. In fact, Sugarman *et al.* states that "liposomal delivery of antitumor therapy is in its ***infancy*** and the optimal liposome/drug formulation has ***not yet been determined.***" Clearly, in view of this statement, one of ordinary skill in the art would understand that using liposomes as carriers of imexon and its derivatives would not reasonably result in success.

Furthermore, combining cancer drug therapies is a highly unpredictable art. Trial and error is often required to determine the proper combination of therapies. For example, Sugarman *et al.* discloses use of liposomes as a carrier for doxorubicin delivered intravenously. In one of the studies, out of 18 patients available for study, only 5 exhibited a ***marginal*** response. Sugarman *et al.*, page 233. These results strongly suggest that success is not even reasonably expected for well-known cancer drugs. As mentioned in the previous section, the prior art, at most, describes an "obvious to try" situation which does not render a claim obvious. Accordingly, the examiner has not established an element necessary for a *prima facie* case of obviousness.

Further, Presant, cited by the Examiner as of interest, which purportedly teaches that liposomes are also called micelles, fails to provide the missing expectation of success. Presant pertains to methods of targeting locations in a body using micellular particles. It contains no information pertaining to delivery of imexon via liposomal delivery.

In view of the examiner's failure to satisfy all three elements needed for a *prima facie* case of obviousness, the Applicants respectfully request that the rejection to claims 1-2 and 4-32 be withdrawn.

3. Rejection of claims 1-2 and 4-32 as being unpatentable over Hermann or WO '120 in view of Presant

Claims 1-2 and 4-32 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hermann or WO '120, in view of Presant. The teachings of Hermann and WO '120 are discussed above. Presant is said to teach that when micellar particles such as liposomes containing active agents are injected into the host, there is an enhanced retention of the active agent in the tumor cells. The examiner contends that the use of micellar particles such as

liposomes for the delivery of imexon taught by Hermann or WO '120 would have been obvious to one of ordinary skill in the art since Presant shows enhanced accumulation of these particles at the tumor site. The examiner further notes that "the criticality of the use of phosphatidylcholine and phosphatidylglycerol with a specific fatty acid chain such as myristic acid in specific ratios is not readily apparent in the absence of unexpected results since there are commonly used phospholipids in the preparation of liposomes." Further, it is said that the use of derivatives of imexon would have been obvious to one of ordinary skill in the art since the active skeleton is the cyanozairidine structure. Applicants traverse.

As discussed in the above 35 U.S.C. §103(a) rejections, in order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. *MPEP* §2142. See also *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed Cir. 1991). All three elements must be shown to establish a *prima facie* case of obviousness. Thus, if even one element is missing, a *prima facie* case of obviousness does not exist.

As previously noted, one of the elements that is required in order for a *prima facie* case of obviousness to exist is that there must be some motivation or suggestion, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the teachings of Hermann or WO '120, in view of Presant. "The mere fact that references can be combined or modified does not render the resultant combination obvious ***unless the prior art also suggests the desirability of the combination***." MPEP § 2143.01

(emphasis added). As in the prior 35 U.S.C. §103 (a) rejections discussed *supra*, none of these references makes any suggestion of delivering imexon via administration of liposomes.

Consequently, the issue is whether one of ordinarily skill in the art, with knowledge that is generally available, would be motivated to combine Hermann or WO '120 and Presant. Applicants assert that, as discussed above in the response to the previously addressed 35 U.S.C. §103(a) rejections, no such motivation to combine these references exists.

The examiner contends that the use of micellar particles such as liposomes for the delivery of imexon taught by Hermann or WO '120 would have been obvious to one of ordinary skill in the art since Presant shows enhanced accumulation of these particles at the tumor site. However, as noted above, hundreds of drugs exist for treating cancer. As discussed above, one of ordinary skill in the art could not possibly know that imexon would be a drug appropriate for liposomal delivery.

Another element in establishing a *prima facie* case of obviousness requires that there be a reasonable expectation that modifying the teachings of WO '120 or Hermann in view of Presant would be successful. As discussed above, applicants submit that there would be no reasonable expectation of success in combining imexon and liposomal delivery in treating cancer. The examiner has failed to provide evidence that modifying or combining the teachings of the cited references would reasonably result in success.

Further, as noted above, the result of combining drug therapies is impossible to predict. The examiner appears to merely assume that combining imexon and liposomal drug delivery will automatically result in success. Once again, there is simply is no basis for such an assumption. Furthermore, none of the cited references provide any guidance or recommendations as to whether combining imexon with liposomal drug delivery would be successful in treating cancer.

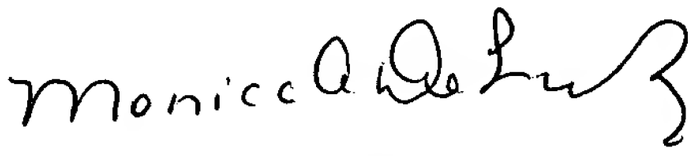
In view of the prior art, a person of ordinary skill in the art could not reasonably expect to achieve success in administering imexon via liposomal delivery. As a result, WO '120 or Hermann in view of Presant does not establish a reasonable expectation of success as required for a *prima facie* case of obviousness.

In view of the above arguments, examiner has not established a *prima facie* case that claims 1-2 and 4-32 were obvious at the time of filing. Accordingly, applicants respectfully request that the rejection of claims 1-2 and 4-32 be withdrawn.

H. Conclusion

Applicants have submitted arguments that are believed to overcome all outstanding rejections. Therefore, allowance of this application is solicited. In the event that the Examiner has suggestions regarding claim amendments or additional information that might speed this case toward allowance, the Examiner is requested to contact the Applicants' representative listed below.

Respectfully submitted,



Monica A. De La Paz
Reg. No. 54,662
Attorney for Applicants

FULBRIGHT & JAWORSKI, L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
512.536.5639

Date: September 14, 2004